DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 24, 2015

BM Korea Company, Limited
% Ms. Priscilla Chung
LK Consulting Group USA, Incorporated
2651 East Chapman Avenue, Suite 110
Fullerton, California 92831

Re: K143110
Trade/Device Name: GALAXY MIS Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: May 26, 2015
Received: May 28, 2015

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143110

Device Name

GALAXY MIS Screw System

Indications for Use *(Describe)*

The GALAXY MIS Screw System is intended to provide immobilization and stabilization of the posterior, non-cervical spine as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. The GALAXY MIS Screw System can be used in an open approach and a percutaneous approach with MIS instrumentation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: June 18, 2015

1. 510K Applicant / Submitter:

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2. Submission Correspondent

Priscilla Chung
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3. Device:

- Proprietary Name – GALAXY MIS Screw System
- Common Name – Pedicle Screw Spinal Fixation System
- Classification Name – Orthosis, spinal pedicle fixation
  Orthosis, spondylolisthesis spinal fixation
  Orthosis, spinal pedicle fixation, for degenerative disc disease

4. Product Code, Classification & Regulation Number:

- NKB (Class III), MNI (Class II), MNH (Class II)
- 21 CFR 888.3070

5. Predicate Device:

- **Primary Predicate Device:**
  - SYNSTER® Pedicle Screw System, SYNSTER® PLUS Pedicle Screw System by BM KOREA Co., Ltd., K120353
- **Additional Predicate Device:**
  - AnyPlus Spinal Fixation System by GS Medical Co., Ltd., K091717
  - Focus Spinal System by L&K Biomed, K112643 and K120140

6. Description:

The GALAXY MIS Screw System consists of GALAXY MIS SCREW (cannulated

polyscrews), GALAXY MIS ROD (straight type rods and pre-bent type rods) and GALAXY Set Screw (set screw components) that can be inserted via percutaneous surgical approach. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy and are fabricated from titanium alloy (ASTM F 136). The implants will be provided non-sterile.

7. Indications for use:

The GALAXY MIS Screw System is intended to provide immobilization and stabilization of the posterior, non-cervical spine as an adjunct to fusion in skeletally mature patients for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. The GALAXY MIS Screw System can be used in an open approach and a percutaneous approach with MIS instrumentation.

8. Non-Clinical Testing:

Static Compression, tension, torsion and dynamic compression bending were performed according to ASTM F1717 and the test results supports that the GALAXY MIS Screw System is substantially equivalent to the predicate devices.

9. Substantial Equivalence:

The GALAXY MIS Screw System is substantially equivalent in design, materials, function, and indications for use, and has similar technological characteristics and principles of operation as the predicate devices. The size range of the predicate devices encompasses that of the subject device. All the devices are provided non-sterile.

There might be difference in design details but the performance test results supported that the subject device is substantially equivalent to the predicate devices.

10. Conclusions:

The subject and predicate devices share the same intended use, primary implant design and equivalent material of manufacture. Based on the test data and the information provided in this 510K submission, the subject device is substantially equivalent to the predicate devices.